VERMONT

Vermont Health Access
Pharmacy Benefit Management Program
DUR Board Meeting Minutes: 01/16/07

Board Members:

Michael Scovner, M.D., Chair
Andrew Miller, R. Ph.
Cheryl Gibson, M.D.
Frank Landry, M.D.
Norman Ward, M.D.
Richard Harvie, R. Ph.
Stuart Graves, M.D.
Virginia Hood, M.D.

Staff:

Ann Rugg, OVHA
David Calabrese, R.Ph., (MHP)
Diane Neal, R.Ph., (MHP)
Scott Strenio, M.D., OVHA
Jennifer Mullikin, OVHA
Nancy Miner, (MHP)
Robin Farnsworth, OVHA
Stacey Baker, OVHA

Guests:

Ann Pezzullo, Cephalon
Carl Pepe, GSK
Carl Possidente, Pfizer
Chris Enfanto, Takeda
Christine Tynun, BIPI
Daniel Martin, Elan
Danielle Moon, Merck
Glenn E. Dooley, Sr, Sanofi-Aventis
Gregg Denton, NovoNordisk
Larry Forti, Pfizer
Jim Kelley, AstraZeneca
Keith Osburn, Sepracor
Keith White, Genentech
Kevin Boehmcke, Abbott
Kevin Danielson, Pfizer
Kirt Hyles, Cephalon
Laura Bartels, TPNA
Maribeth Klettke, Sanofi-Aventis
Matt Badalucco, Merck
Matthew Sasso, Sanofi-Aventis
Michael Gaidys, Merck
Michael Zdrojewski, ScheringPlough
Paul Fanikos, BIPI
Ronald Poppel, BMS
Sarah Karish, Boehringer-Ingelheim
Stacy Feeney, Cephalon
Thomas Algozzine, Pfizer
Tom Madson, Eli Lilly

Michael Scovner, M.D., Acting Chair, called the meeting to order at 7:10 p.m. at the DUR Board meeting site in Williston.

1. Executive Session:

- An executive session was held from 6:30 until 7:00 p.m. to discuss Medicaid OBRA'90/Supplemental Rebates and Agreements as provided by 33 VSA § 1998(f)(2).

2. Introductions and Nominations and Election of Chair:

- Introductions were made around the table.
- Michael Scovner, M.D., graciously agreed to act as Chair for this meeting.
- Nominations for a permanent Chair were accepted.
- Michael Scovner, M.D. was elected unanimously as permanent Chair of the board.

Public Comment: No public comment.

3. Approval of DUR Board Minutes:

- The December 2006 meeting minutes were accepted as printed without amendment.

4. OVHA Pharmacy Administration Updates: *Ann Rugg - Deputy Director, OVHA*

- Auditor of Accounts Report: In December, the Auditor of Accounts issued a report that identified a possible 2.2 million dollars in improper payments in pharmacy claims processing for the period 1/1/04 – 12/31/05. The audit reviewed claims that were available from EDS and were not pulled from the full claims file. The full claims file is being obtained from First Health so that information such as prior authorizations and overrides can be examined.
- Medicare Modernization Act (Medicare Part D): Year 2 has been proceeding much more smoothly than last year. OVHA continues to resolve claims from the prior year. Greater than 5 million dollars has been collected to date with about 6 million dollars outstanding in claims to be collected from CMS or the Part D plans.

5. Medical Director Update: *Scott Strenio, M.D. – Medical Director, OVHA*

- No updates, prescriber comments, or other topics for discussion.

6. Follow-up items from Previous Meeting

- Anti-infectives: Topical: *Diane Neal, R.Ph, MedMetrics Health Partners (MHP)*
  Topical anti-infectives were presented as a new drug category to be added to the PDL at the December meeting. At that time, it was realized that mupirocin generic ointment had not been addressed. A revised drug category listing that included mupirocin generic ointment as a preferred product was presented.

Public Comment: No public comment.

Board Decision: The Board voted unanimously to add mupirocin generic ointment to the PDL.

7. Review of Newly-Developed/Revised Clinical Coverage Criteria:

Note: All drug/criteria decisions will be reflected in the next PDL and/or Clinical Criteria update.

- Antihypertensives: ACE Inhibitors: *David Calabrese, R.Ph, (MHP)*
  The revised clinical criteria were presented. No changes were made in the preferred or non-preferred products. This represents a more streamlined set of criteria. Specific criteria for Altace® were removed. All ACE inhibitors will be treated in a comparable fashion.

Public Comment: No public comment.

Board Decision: The revised clinical criteria were unanimously accepted.

- Antihypertensives: Angiotensin Receptor Blockers and ARB Combinations: *David Calabrese, R.Ph, (MHP)*
  The revised clinical criteria were presented. A recommendation was presented for a requirement of a step through a generic ACE inhibitor before being eligible for treatment with an ARB. There are currently no studies that show superior outcomes with treatment with an ARB as compared to an ACEI. There are a number of generic ACEI available while all ARBs are branded products. These criteria would allow patients to be on an ACEI and an ARB simultaneously. Existing patients currently receiving an ARB would be grandfathered and the revised criteria would affect new starts only. To get to a non-preferred ARB there will be a requirement for an ACEI first followed by a preferred ARB.

Public Comment: Sarah Karish, Boehringer-Ingelheim - Commented on the 24 hour efficacy of Micardis® (telmisartan).

Michael Gaidys, Merck – Commented on the use of Cozaar® (losartan) in diabetic nephropathy in both type 1 and type 2 diabetics and also on the stroke risk reduction with Cozaar®. He also commented on the FDA approved indication of first line therapy for severe hypertension for Hyzaar (losartan/hydrochlorothiazide).

Ron Poppel, BMS – Requested consideration of moving ARBs that are now non-preferred to the preferred side of the PDL in light of the new step therapy edit.

Board Decision: The Board requested that the length of authorization be changed from one year to lifetime. The step will be automated so that there will be a look back for 180 days to detect a claim for an ACEI before requirement of a PA. The revised clinical criteria with the requested changes were unanimously accepted.

- Lipotropics: *Diane Neal, R.Ph, (MHP)*
  Clinical criteria for this drug class were not changed. The category was simply divided into more manageable subcategories. Combination products were moved to a "miscellaneous/combinations" subcategory. The clinical criteria for Pravacard PAC® and Caduet® were clarified to require justification of the use of a combination product.

Public Comment: No public comment.

Board Decision: The revised clinical criteria were unanimously accepted.

- Pulmonary: Leukotriene Modifiers *Diane Neal, R.Ph, (MHP)*
  The revised clinical criteria were presented. No criteria for approval of Zyflo® had been included in the past. The criteria will now be that "the patient has a documented side effect, allergy, or treatment failure to both Accolate® and Singulair®".

Public Comment: No public comment.

Board Decision: The revised clinical criteria were unanimously accepted.

8. Clinical Update: New Drug Reviews: *Diane Neal, R.Ph.(MHP)*

- Daytrana® (methylphenidate transdermal system) – Not recommended for addition to the PDL. Coverage would require PA with a diagnosis of ADHD and a medical necessity for the transdermal formulation (i.e. swallowing disorder, difficulty taking oral medication). Convenience would not be a valid reason for approval. A quantity limit of 1 patch/day was recommended.

Public Comment: No public comment.

Board Decision: The Board approved the MHP recommendations noted above with the addition of a minimum age of 6 years.

9. New Drug Classes:

Note: All drug/criteria decisions from this section will be reflected in the **02/01/07** PDL and/or Clinical Criteria update unless specified otherwise.

- Smoking Cessation: Nicotine Replacement/Oral *Diane Neal, R.Ph, (MHP)*
  A new drug review of Chantix® (varenicline) was presented. There was concern about establishing a coordinated approach with the Vermont Department of Health smoking cessation program. It was suggested that perhaps beneficiaries could enroll with the VT Department of Health Quit Line to encourage behavior modification.

Public Comment: No public comment.

Board Decision: The Board chose to defer approval of Chantix® and the smoking cessation drug class until next month and asked for additional information regarding the Vermont Department of Health smoking cessation program and tobacco settlement monies. The Board requested that Dr. Ted Marcy who is an expert in the field of smoking cessation be contacted and invited to attend next month's meeting. Chantix® will continue to be managed as "PA required – new to market" until next month's meeting.

- Constipation: Chronic *Diane Neal, R.Ph, (MHP)*
  A new drug review of Amitiza® (lubiprostone) was presented. It was not recommended for addition to the PDL. Coverage would require PA with a diagnosis of chronic idiopathic constipation and a failure of conventional therapies (dietary and lifestyle modifications) and a 1 week trial of 2 preferred chronic constipation laxatives.
  A new drug review of Zelnorm® (tegaserd maleate) was presented. It was not recommended for addition to the PDL. Coverage would require PA with a diagnosis of chronic idiopathic constipation in men or women or constipation-predominant IBS in women, a failure of conventional therapies (dietary and lifestyle modifications) and a 1 week trial of 2 preferred chronic constipation laxatives. Existing users would be grandfathered.
  The new Constipation: Chronic category was presented. Proposed PDL preferred agents as recommended by the American College of Gastroenterology Chronic Constipation Task Force to include psyllium, lactulose and polyethylene glycol 3350.

Public Comment: Chris Enfanto, Takeda - Confirmed that Amitiza® does not alter electrolyte concentrations in patients.

Board Decision: The Board approved as recommended.

- Chemical Dependency Treatments *Diane Neal, R.Ph, (MHP)*
  A new drug review of Vivitrol® Injection (naltrexone) was presented. It was not recommended for addition to the PDL. Coverage would require PA with a diagnosis of alcohol dependency and an inadequate response, adverse reaction, or contraindication to 2 out of 3 oral formulations used for alcohol dependence including: oral naltrexone, acamprosate, and disulfiram.

Public Comment: Kirt Hyles, Cephalon – Discussed the use of Vivitrol® in patients who are not compliant with oral naltrexone therapy. The use of specialty pharmacy for the provision of Vivitrol® direct to physician offices was also explained. The company provides medical alert cards to patients who are receiving this medication.

Board Decision: The Board deferred making a decision at this meeting and requested a presentation by an addiction expert.

- Methadone – FDA Alert *Diane Neal, R.Ph, (MHP)*
  A FDA alert for healthcare professionals was discussed. The FDA is alerting prescribers to incidents of death, narcotic overdose, and serious cardiac arrhythmias with the use of methadone. Included in the alert was a recommendation to not use methadone 40 mg dispersable tablets for pain.

Public Comment: No public comment.

Board Decision: The Board recommended putting a soft edit in the pharmacy claims system for 1 month and then to reject claims for 40 mg dispersable methadone tablets with PA required.

- Lipotropics: Bile Acid Sequestrants *David Calabrese, R.Ph, (MHP)*
  Proposed PDL preferred agents to be generic cholestyramine powder, cholestyramine light powder, Prevalite powder and colestipol tablets and granules.
  Proposed non-preferred (PA required) agents to include all the branded products Questran® powder, Questran Light® powder, Colestid® tablets and granules and Welchol®.
  Clinical criteria for approval of non-preferred agents were presented.

Public Comment: No public comment.

Board Decision: The Board approved as recommended with a requested change in the length of authorization from one year to lifetime.

- Anti-Infectives: Penicillins (Oral) *Diane Neal, R.Ph. (MHP)*
  Proposed PDL preferred agents to be generic amoxicillin, amoxicillin/clavulanate, ampicillin, dicloxacillin and penicillin VK.
  Proposed non-preferred (PA required) agents to include the branded products Augmentin®, Augmentin ES®, and Augmentin XR®. No PA would be required for the 125 mg/5 ml strength of Augmentin® in beneficiaries < 12 weeks of age.
  Clinical criteria for approval of non-preferred agents were presented.

Public Comment: No public comment.

Board Decision: The Board approved as recommended with the criteria for Augmentin XR® amended to read "the prescriber must provide a clinically valid reason for the use of the requested medication".

- Psoriasis: Non-Biologics (Oral/Topical) *Diane Neal, R.Ph. (MHP)*
  Proposed oral PDL preferred agents to be cyclosporine, methotrexate, Oxsoralen-Ultra® and Soriatane®. There are no proposed non-preferred oral products.
  Proposed topical PDL preferred agents to be Dovonex®, Psoriatec®, Dritho-Scalp® and Tazorac®. Proposed non-preferred (PA required) topical agent is Taclonex® with clinical criteria for approval as established at the December 2006 meeting.

Public Comment: No public comment.

Board Decision: The Board approved as recommended.

10. RetroDUR: *Diane Neal, R.Ph. (MHP)*

- Extensive use of a short-acting beta-agonist and no concomitant controller medication – 120 patients were identified in June 2006 with patient specific letters sent to physicians. Of these, 53 patient specific faxes were sent to pharmacies in October 2006 when no response was received from the physician or the correct physician could not be identified. A review of claims history in November 2006 revealed that 29 patients (24 %) were now receiving controller medication, but 78 patients (65 %) had no change in therapy. 13 patients (11 %) were inappropriately targeted or lost to follow-up.

- Long acting beta-agonist use with no controller medication – 32 patients were identified in July 2006 with patient specific letters sent to physicians. Of these, 18 patient specific faxes were sent to pharmacies in October 2006 when no response was received from the physician or the correct physician could not be identified. A review of claims history in November 2006 revealed that 11 patients (34 %) were now receiving controller medication, but 13 patients (41 %) had no change in therapy. 4 patients (12 %) were inappropriately targeted or lost to follow-up. 4 patients (12 %) showed no utilization of any asthma medication or no utilization of a long-acting beta-agonist which may also represent an intervention.

- Combination atypical antipsychotic therapy for greater than a 60 day period, excluding clozapine therapy – Response rate by prescribers to this mailing was 40 %.
  6 % of mailings were undeliverable. 13 % of responders indicated they would review therapy with the patient either by setting up an appointment or at the next scheduled visit. 55 % of responders chose not to intervene in therapy, primarily because the patient has been tried on multiple monotherapies and did not adequately respond or the medication regimen was recommended by another provider. 13 % of responders either discontinued a medication or were in the process of tapering a medication off. 18 % of responders indicated that either this was not their patient or they were no longer treating the patient.

- Long Acting Narcotics – Claims history from 10/01/06 – 01/10/07 was examined to look for 2 or more prescriptions for long acting narcotics and/or buprenorphine. 102 patients were identified with 19 potential problems of overlap/duplication revealed. The issues include the use of a fentanyl transdermal patch while also taking oral long acting narcotics, the use of 2 or more oral long acting narcotics, and/or the use of more than one physician or pharmacy. The Board recommended comparing these patients to patients identified by the already established "profiler" system and sending an informational letter to physicians.

11. Updated New-to-Market Monitoring Log: *Diane Neal, R.Ph, (MHP)*

- This log shows new entries in the market highlighted in red. The log is informational only. Suggested dates for review are to be used as a guide only. The actual date of review will depend on the complexity of the agenda.

Public Comment: No public comment.

Board Decision: The Board approved all MHP recommendations.

12. General Announcements:

- No announcements.

13. Adjourn: Meeting adjourned at 9:25 p.m.

Next DUR Board Meeting
Tuesday, February 13, 2007
7:00 - 9:00 p.m.*
EDS Building, OVHA Conference Room
312 Hurricane Lane, Williston, VT
(Entrance is in the rear of the building)

* The Board meeting will begin at 6:30 p.m. and the Board will vote to adjourn to Executive Session to discuss Medicaid OBRA'90/Supplemental Rebates and Agreements as provided by 33 VSA § 1998(f)(2). The Executive Session is closed to the public.